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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,194	01/08/2001	Graham P Belfield	3525-119	7361

7590 08/13/2002
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EXAMINER
LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,194

Applicant(s)

BELFIELD ET AL.

Examiner

Gerald Leffers

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2002.
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 11-18, 20 and 22-29 is/are rejected.
- 7) ☒ Claim(s) 7, 10, 19 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicants' election of Group IV (claims 1-29) in Paper No. 5, filed 5/31/02, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The examiner thanks applicants for noting the typographical error in the restriction requirement. Applicants are correct in that Group IV is drawn to SEQ ID NO: 4 rather than SEQ ID NO: 1. Claims 1-29 have been examined accordingly.

Information Disclosure Statement

Receipt is acknowledged of an information disclosure statement (IDS) filed 5/31/02 as Paper No. 4. The signed and initialed PTO Form 1449 has been mailed along with this action. The four search results (e.g. "B-Door External...") have not been considered as there is no indication of their publication date or where the information is available to the public (i.e. publisher). If applicants want the information therein to be considered, the information should be resubmitted in a form consistent with 37 CFR §1.98. It is noted, however, that the results for SEQ ID NO: 4 have already been obtained and considered as part of the examiner's search of the sequence databases.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Compositions and Methods Utilizing the Yeast ZEO1 Promoter.

The disclosure is objected to because of the following informalities: at several places in the specification there are odd placements of letters and symbols at the beginning and ending of words. For example, on page 2 at lines 5 & 6, the term "Ayeast promoter@" is used. It appears that the characters "A" and "@" are meant to be quotation marks around the words "yeast promoter". Similarly, on page 25 at line 14, the phrase "the genomic sequence 5= to the following ORFs" is used. It appears the phrase is meant to specify genomic sequences 5 prime to the recited ORFs. Numerous instances of these typographical errors are present throughout the specification. It would be remedial to amend the specification in each instance to clearly indicate what is intended.

Appropriate correction is required.

Claim Objections

Claims 1-29 are objected to because of the following informalities: each of the claims is drawn towards non-elected embodiments of the claimed invention (e.g. SEQ ID NOS: 1-3). It would be remedial to amend the claim language to only refer to the elected embodiments (i.e. SEQ ID NO: 4; pZEO1P and pZEO1P+luc). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-9, 11-18, 20, 22-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn towards a yeast promoter, vectors and host cells comprising the promoter and methods of expressing a protein featuring the promoter, where the promoter comprises at least 17 contiguous nucleotides of SEQ ID NO: 4 and wherein the promoter is operative to express a nucleic acid molecule encoding a polypeptide when operatively linked thereto. The promoter can be operative in any cell type (e.g. claims 1-6) or must at least be operative in yeast (e.g. claim 8). The promoter may have at least 50, 100, 200, 300 or 400 nucleotides of SEQ ID NO: 4, or the entire 500 nucleotide sequence of SEQ ID NO: 4. For many of the claims the level of promoter activity is controlled by the level of fermentable carbon source (e.g. glucose) and/or non-fermentable carbon source (ethanol) in the culture medium.

SEQ ID NO: 4 describes a 500 nucleotide sequence. Even for an embodiment featuring a promoter comprising at least 400 contiguous nucleotides of SEQ ID NO: 4, there are a very large number of possible fragments that may or may not retain promoter activity. As the number of contiguous nucleotides of SEQ ID NO: 4 that must be present in the claimed promoter or promoter fragment decreases, the number of possible fragments that must function as a promoter greatly increases (e.g. 17 contiguous nucleotides out of 500). Thus, the claims are broad genus claims encompassing a large number of fragments that must retain promoter activity. The size of

the genus is further compounded by the functional limitation in at least some of the claims that the promoter must be responsive to fermentable and non-fermentable carbon sources in culture media.

SEQ ID NO: 4 is 500 nucleotides in length and describes a sequences that is found at the 3' end of the yeast open reading frame YOL110W and extends to the beginning of the YOL109W (ZEO1) reading frame (Figure 32 of the instant specification). The specification describes the cloning of SEQ ID NO: 4 into an expression vector with a reporter polypeptide (luciferase) to demonstrate that the sequence described by SEQ ID NO: 4 possesses promoter activity and that the promoter activity is responsive to both glucose and ethanol in culture media (Table 7). No description is provided in the specification of any fragment of SEQ ID NO: 4 of any length that retains promoter activity. No description is provided in the specification of any sequence within SEQ ID NO: 4 that resembles a known transcription factor binding sequence (e.g. GAL4, etc.). The specification provides no guidance with regard to which fragments within SEQ ID NO: 4 might be essential for response to fermentable or non-fermentable carbon sources within the culture media.

The prior art does not offset the deficiencies of the instant specification with regard to description of the claimed invention. Promoter sequences comprising SEQ ID NO: 4 do not appear to have been described in the prior art. While one of skill in the art might be able to identify sequences within SEQ ID NO: 4 that possess some homology to binding sites for known transcription factors, there may well be other unknown transcription factors required for even the basal level of promoter activity associated with SEQ ID NO: 4, much less glucose- or ethanol-

responsive activities. Again, there is no description in the art of record for regulatory sequences to express ZEO1 in yeast.

Given the great number of possible fragments of SEQ ID NO: 4 encompassed by the rejected claims and the limitation that the fragments must retain at least some functional activity, and given the lack of a structural/functional basis provided by the instant specification or prior art for one of skill in the art to envision those embodiments that actually do retain promoter activity, the skilled artisan would not have been able to envision a sufficient number of the claimed embodiments to describe the broadly claimed genus. Therefore, the skilled artisan would have reasonably concluded that applicants were not in possession of the claimed invention.

Conclusion

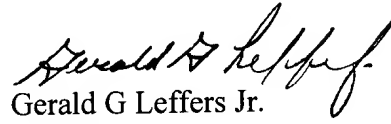
Claims 1-6, 8-9, 11-18, 20 and 22-28 are rejected. Claims 7, 10, 19 and 21 are objected to as being drawn towards nonelected embodiments. Claims 10 and 19 are further objected to as being dependent upon a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gerald G Leffers Jr.

Examiner

Art Unit 1636

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August 11, 2002